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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,291	03/01/2004	G. Barrie Kitto	CLFR:232US	9495

7590 05/26/2006

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EXAMINER	
WORLEY, CATHY KINGDON	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,291	KITTO ET AL.	
	Examiner	Art Unit	
	Cathy K. Worley	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *7-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/4/05; 5/31/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

1. In response to the communication received on May 8, 2006 from David L. Parker, the election without traverse of group I, claims 1 and 3-6 as they relate to mouse lactate dehydrogenase, is acknowledged. The Applicant has withdrawn the non-elected claims, however, claim 2 is a linking claim, and therefore it will be examined along with claims 1 and 3-6. All claims should be amended to read only on the elected subject matter.

2. Because claim 2 has an improper designator, Applicants are required to submit a new copy of the claims with the proper designators.

Specification

3. The use of the following trademarks has been noted in this application: TITERMAX, QIAPREP, CELL PORATOR, GENE AMP, TWEEN, EPPENDORF, DIAFLO, SORVALL, WHATMAN. They should be written in all capital letters wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Information Disclosure Statement

4. The listing of references in the specification on pages 73-74 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites "wherein said antigenic fragment is selected from the group consisting of amino acids 5-17, 44-58, 61-77, 97-110, 180-210, 211-220, 231-243, 283-306, 307-316, and 101-115 of murine lactate dehydrogenase-C". It is unclear which

murine lactate dehydrogenase-C (LDH-C) is being claimed, and different GenBank Accessions have different amino acid sequences. Is this the amino acid sequence of GenBank Accession 2LDX? Or is this the amino acid sequence of GenBank Accession NP_038608? Or is this some mouse LDH sequence not present in any databases?

6. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a genetically modified plant that expresses an immunocontraceptive comprising a sperm-specific polypeptide or an antigenic fragment thereof. The instant application has not described the full genus of any sperm-specific proteins that can act as immunocontraceptives. The instant application does not describe any sperm-specific polypeptides other than LDH-C, nor has the application described "antigenic fragments" thereof as recited in claim 2. Claim 5 is drawn to a transgenic plant expressing an antigenic fragment selected from the group consisting of amino acids 5-17, 44-58, 61-77, 97-110, 180-210, 211-220, 231-243, 283-306, 307-316, and 101-115 of murine lactate dehydrogenase-C. Because the complete amino acid sequence for murine lactate dehydrogenase-C is

not described in the specification, none of these peptides are sufficiently described. In the 112 2nd paragraph rejection, above, the Examiner points out that different GenBank Accessions of murine LDH-C will have different amino acid sequences. Therefore, the peptides claimed in claim 5 are not described adequately because the sequences will differ depending on which full-length amino acid sequence is used as a reference for the fragments recited in the claim.

7. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a genetically modified plant that expresses an immunocontraceptive comprising a sperm-specific polypeptide or an antigenic fragment thereof, including a transgenic plant expressing an antigenic fragment selected from the group consisting of amino acids 5-17, 44-58, 61-77, 97-110, 180-210, 211-220, 231-243, 283-306, 307-316, and 101-115 of murine lactate dehydrogenase-C.

The nature of the invention is a molecular biological approach for producing an immunocontraceptive peptide in a transgenic plant.

The prior art teaches that immunocontraceptives can be produced in plants, however, for the reasons stated in the 112 2nd rejection and the written description rejection, above, one of skill in the art would not know which amino acid sequences are encompassed by the recitation of "sperm-specific polypeptide" in claim 1 or "fragment thereof" in claim 2 or the specified amino acids in claim 5. Therefore, one of skill in the art would not know how to make such plants.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bleil et al. (WO 98/00440, published on Jan. 8, 1998).

Claims 1 and 6 are drawn to a genetically modified plant that expresses an immunocontraceptive comprising a sperm-specific polypeptide.

Bleil et al. teach transgenic plants expressing mammalian sp56, a sperm-specific protein that is antigenic and can be used as an immunocontraceptive (see abstract and page 21 lines 32-34). Bleil et al. teach that preferred plants include tobacco, corn, wheat, and rice (see page 37 lines 10-11).

9. Claims 1-2 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Kirk et al. (Pre-Grant Publication: US 2004/0175440 A1, published on Sept. 9, 2004; application No. 10/683,611, filed on Oct. 10, 2003 with priority to PCT/US02/11693 which was filed on April 12, 2002).

Claims 1-2 and 6 are drawn to a genetically modified plant that expresses an immunocontraceptive comprising a sperm-specific polypeptide, including lactate dehydrogenase-C or an antigenic fragment thereof.

Kirk et al. teach transgenic plants expressing the immunocontraceptive lactate dehydrogenase (see page 37, claim 40), and they teach rice plants, wheat plants, and corn plants (see page 37, claim 48).

10. Claims 1-2 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Kirk et al. (WO 02/083072 A2, published on Oct. 24, 2002).

Claims 1-2 and 6 are drawn to a genetically modified plant that expresses an immunocontraceptive comprising a sperm-specific polypeptide, including lactate dehydrogenase-C or an antigenic fragment thereof.

Kirk et al. teach transgenic plants expressing lactate dehydrogenase, including rice plants, wheat plants, and corn plants (see page 87, claims 40 and 48).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bleil et al. (WO 98/00440, published on Jan. 8, 1998) in view of Goldberg et al.(Adv Exp Med Biol. (1986) Vol. 207, pp. 395-406).

Claims 1-6 are drawn to a genetically modified plant that expresses an immunocontraceptive comprising a sperm-specific polypeptide, including lactate dehydrogenase-C (LDH-C) or an antigenic fragment thereof, including mouse LDH-C or antigenic fragments thereof.

Bleil et al. teach transgenic plants expressing a sperm-specific polypeptide as discussed above in the 102(b) rejection.

Bleil et al. do not teach LDH-C or mouse LDH-C or antigenic fragments thereof.

Goldberg et al. teach mouse LDH-C and antigenic fragments thereof (see page 402, figure 3).

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to make transgenic plants such as the ones taught by Bleil et al, modified such that they expressed the mouse LDH-C or antigenic fragments thereof taught by Goldberg et al. One would have been motivated to do so because Goldberg et al. teach that LDH-C is a very effective

immunocontraceptive (see abstract and page 396 second paragraph). Because claim 1 uses the open language of "comprising a sperm-specific polypeptide", the expression of the full-length murine LDH-C anticipates claim 5 because the full-length LDH-C "comprises" each of the fragments recited in claim 5.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claims 1-6 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 of copending Application No. 10/664,118. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW
May 17, 2006

ANNE KUBELIK, PH.D.
PRIMARY EXAMINER